

Food and Drug Administration, HHS

§ 21.30

(10) Where any records in the system are subject to an exemption under § 21.61, a reference to this exemption.

(11) The categories of sources of records in the system.

[42 FR 15626, Mar. 22, 1977, as amended at 46 FR 8457, Jan. 27, 1981]

§ 21.21 Changes in systems and new systems.

(a) The Food and Drug Administration shall notify the designated Department official, the Office of Management and Budget (Information Systems Division), and the Congress of proposals to change or establish Privacy Act Record Systems in accordance with procedures of the Department and the Office of Management and Budget.

(b) The Food and Drug Administration shall issue a notice, in accordance with paragraph (d) of this section and § 21.20(b), of any change in a Privacy Act Record System which:

(1) Increases the number or types of individuals about whom records are maintained;

(2) Expands the type or amount of information about individuals that is maintained;

(3) Increases the number of categories of agencies or other persons who may have access to those records;

(4) Alters the manner in which the records are organized so as to change the nature or scope of those records, such as the combining of two or more existing systems;

(5) Modifies the way in which the system operates or its location(s) in a manner that alters the process by which individuals can exercise their rights under this part, such as the ways in which they seek access or request amendment of a record; or

(6) Changes the equipment configuration on which the system is operated so as to create the potential for greater access, such as adding a telecommunications capability.

(c) The Food and Drug Administration shall issue a notice of its intention to establish new Privacy Act Record Systems in accordance with paragraph (d) of this section and § 21.20(b).

(d) Notices under paragraphs (b) and (c) of this section shall be published in the FEDERAL REGISTER for comment at

least 30 days prior to implementation of the proposed changes or establishment of new systems. Interested persons shall have the opportunity to submit written data, views, or arguments on such proposed new uses or systems.

Subpart C—Requirements for Specific Categories of Records

§ 21.30 Records of contractors.

(a) Systems of records that are required to be operated, or as a matter of practical necessity must be operated, by contractors to accomplish Food and Drug Administration functions, from which information is retrieved by individual names or other personal identifiers, may be subject to the provisions of this part. If the contract is agreed to on or after September 27, 1975, the criminal penalties set forth in 5 U.S.C. 552a(i) are applicable to such contractor, and any employee of such contractor, for disclosures prohibited in § 21.71 or for maintenance of a system of records without notice as required in § 21.20.

(b) A contract is considered to accomplish a Food and Drug Administration function if the proposal or activity it supports is principally operated on behalf of and is under the direct management of the Food and Drug Administration. Systems of records from which information is retrieved by individual names or other personal identifiers and that are operated under contracts to accomplish Food and Drug Administration functions are deemed to be maintained by the agency and shall be subject to the procedures and requirements of this part.

(c) A contract is not considered to accomplish a Food and Drug Administration function if the program or activity it supports is not principally operated on behalf of, or is not under the direct management of, the Food and Drug Administration. For example, this part does not apply to systems of records:

(1) Operated under contract with the Food and Drug Administration by State or local government agencies, or organizations representing such agencies, when such agencies or organizations are also performing State or local government functions.